ESTABLISHING AN OBSERVATIONAL MPOX VACCINATION STUDY WHILE THE OUTBREAK EVOLVES

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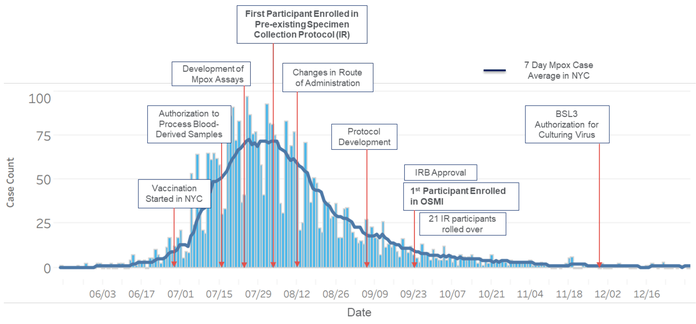
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BACKGROUND

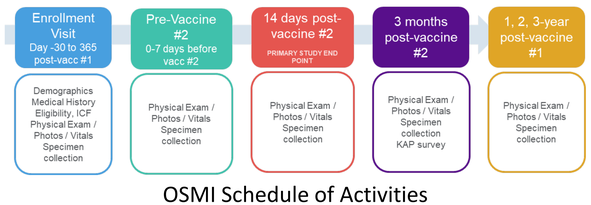
The mpox outbreak of 2022 disproportionally and rapidly affected men, the LGBTQ+ community, and people living with HIV (PLWH). NYC was declared the nation's epicenter, with 3,821 cases reported as of January 15, 2023. NYC rolled out a Jynneos™ vaccination program, initially with full doses delivered subcutaneously (SC), then with low doses intradermally (ID)—to increase the total number of doses available. However, ID route had not been evaluated in PLWH. **This study was developed to assess the immunogenicity, tolerability, and safety of SC and ID mpox vaccinations in those with and without HIV.**

METHODS

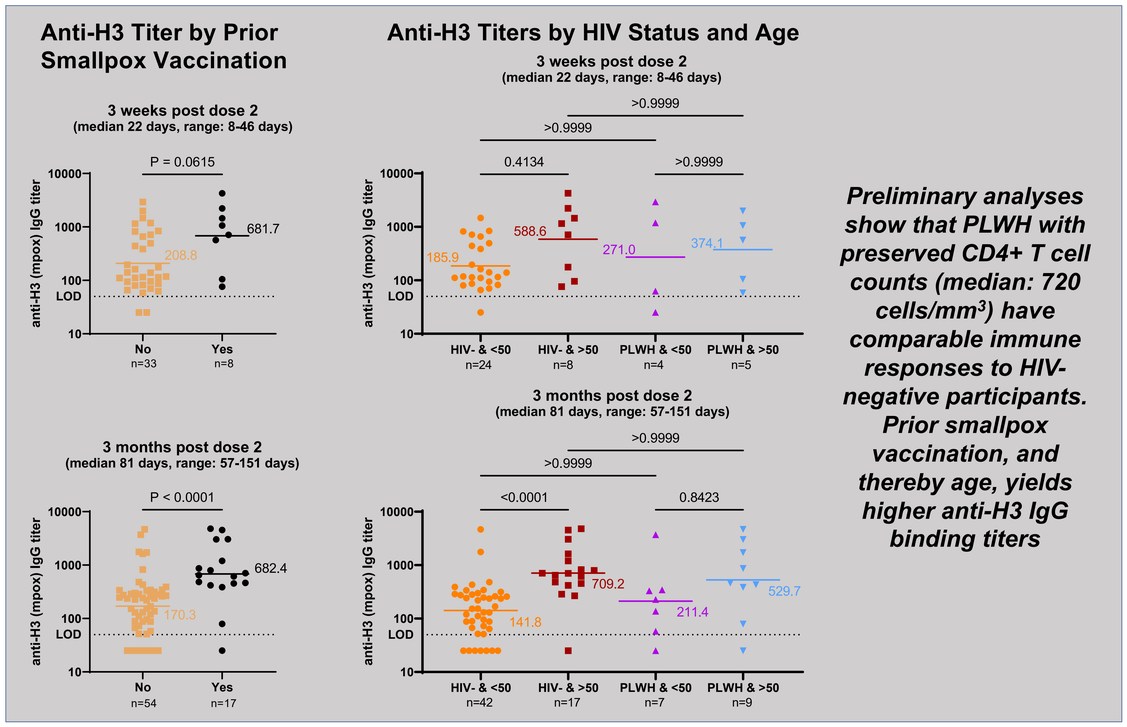
A longitudinal, observational study of adults (PLWH and HIV-) who have received the JYNNEOS vaccine or with history of mpox infection in NYC was rapidly established (Observational Study of Mpox Immunity, OSMI). Immunogenicity endpoint is measured as the GMT of serum neutralization of mpox live virus; mpox-specific binding IgG titers are a secondary endpoint (measured by ELISA). Tolerability is assessed through a reactogenicity diary. Safety is monitored by capturing adverse events (AE) and serious AE (SAE). Vaccine acceptability is measured via a knowledge, attitudes, and practices (KAP) survey. Up to 300 participants will be enrolled. Statistical significance was analyzed by Mann-Whitney (two-group), Kruskal-Wallis (multiple comparisons), or linear regression.



Key Dates in NYU Vaccine Center Mpox Response During NYC Outbreak



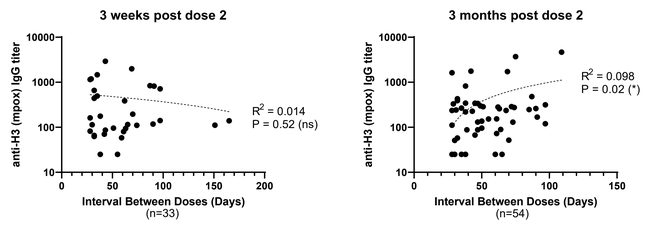
OSMI Schedule of Activities



Preliminary analyses show that PLWH with preserved CD4+ T cell counts (median: 720 cells/mm³) have comparable immune responses to HIV-negative participants. Prior smallpox vaccination, and thereby age, yields higher anti-H3 IgG binding titers

	Total	PLWH	(%)	HIV-	(%)
Enrolled Participants	100	24.0	24.0	76	76.0
Gender					
Male	87	23	95.8	64	84.2
Female	10	0	0.0	10	13.2
Non-binary/Gender Fluid/Queer	3	1	4.2	2	2.6
Age					
Median	45.6	49.7	n/a	41.4	n/a
49 and younger	67	11	45.8	56	73.7
50 and older	33	13	54.2	20	26.3
Race/Ethnicity					
White	63	11	45.8	52	68.4
Black or African American	12	5	20.8	7	9.2
Asian	12	4	16.7	8	10.5
American Indian/Alaska Native	4	1	4.2	3	3.9
Other	9	3	12.5	6	7.9
Non-Hispanic	74	17	70.8	57	75.0
Hispanic	24	7	29.2	17	22.4
Other	2	0	0.0	2	2.6
Administration Route					
SC-SC	14	3	12.5	11	14.5
ID-ID	22	4	16.7	18	23.7
SC-ID or ID-SC	56	12	50.0	44	57.9
Incomplete	8	5	20.8	3	3.9
Prior Smallpox Vaccination					
Yes	24	9	37.5	15	19.7
No	69	13	54.2	56	73.7
Unknown	7	2	8.3	5	6.6
Reactogenicity Reported					
Subcutaneous Dose	52	8	38.1	44	65.7
Intradermal Dose	91	17	85.0	74	92.5
1st Dose	70	12	54.5	58	77.3
2nd Dose	73	13	68.4	60	83.3

Anti-H3 Titers by Dose Interval (Excluding Prior Smallpox Vaccinees)



RESULTS

As of February 9, 2023, 100 participants have been enrolled, median age is 45 years, 33% are 50-year-old or older, 24% are PLWH (median CD4 count 720), most identify as male (87%) and as LGBTQ+ (92%), with diverse ethnic backgrounds (63% White, 12% Asian, 12% Black/African American, 13% Native or other races; and 24% Hispanic or Latino ethnicity). SC-ID was the most common combination route of administration (50%). 24% had a known prior history of smallpox vaccination. Reactogenicity was similar between 1st and 2nd dose. ID route was the most reactogenic. Most common symptoms reported were redness, pruritus, and swelling. No SAE have been reported. Preliminary immunogenicity data shows **no significant differences** in mpox-specific binding IgG antibody titers **between PLWH and HIV- participants** regardless of the route of administration (by non-parametric Kruskal–Wallis multiple comparisons), however there were **higher binding antibody titers among participants with history of prior smallpox immunization and age >50y/o,** the latter related to the high percentage of prior smallpox vaccination in this study population. In addition, there is a significant correlation between dosing interval and anti-H3 IgG binding titers at 3 months post second dose.

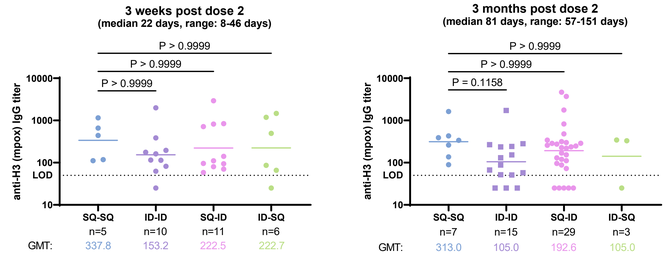
CONCLUSIONS

Rapid implementation of vaccine studies that respond in real-time to epidemics and include disproportionally-affected populations are an integral part of the public health response. The data resulting from this study will fill knowledge gaps, inform public health practices, guide policymakers, and address community concerns regarding the absence of data for low-dose ID vaccinations in PLWH. Preliminary antibody data suggest PLWH with preserved CD4+ T cell counts respond well to the vaccine.

ADDITIONAL KEY INFORMATION

This work was generously supported by the Blavatnik Family Foundation and NYU Grossman School of Medicine. The OSMI Study Group includes Abdul Abdulai, Hayley Belli, Jacqueline Callahan, Tamia Davis, Amanda Dontino, Aimee Edwin, Emilie Geesey, Shelby Goins, Sarah Haiken, Hye-Youn Kim, Dorothy Knutsen, Irma Noriega, Samuel Nweke, Madalyn Saporito, Pamela Suman, Meron Tasissa, Michael Tuen, James Wilson, Grace Yip, Samantha Yip, and Miilani Yonatan.

Anti-H3 Titers by Route of Administration (Excluding Prior Smallpox Vaccinees)



New York University Vaccine Center: Protecting and Restoring Health Through Vaccine Research